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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/770,901	01/26/01	FAOUR J	PHUS-28

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HM22/0928

EXAMINER	
JIANG,S	
ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/770,901	FAOUR ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-38* is/are pending in the application.

4a) Of the above claim(s) *9 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 1-8 and 10-38 and the invention of the species of rofecoxib as a COX-II inhibitor and pridinol as a muscle relaxant, in Paper No. 7 submitted August 31, 2001 is acknowledged.

Claims 9 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The claims have been examined insofar as they read on the elected specie.

Claim Objection

Claims 7-8 and 16-17 are objected to for minor informalities. The employment of parenthetical expressions e.g., "(SOMA^{R})", "(pridinolum)", and "(6-MNA)" in the claims is considered informal. Appropriate correction is required.

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that recitation of an inherent property of a composition will not further limit claims drawn to a composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-8, 12, 14, 16-18, 22-23, 28-29, and 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions "slow or rapid release" in claim 12, "rapidly" in claim 18, "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release.." in claim 29, and "rapid release" or "a delayed but rapid release" in claims 31-37, renders claims 12, 18, 29, and 31-37 indefinite. The expressions "slow or rapid release", "rapidly", "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release..", and "rapid release" or "a delayed but rapid release" are not defined by the claims. Therefore, the scope of claims is indefinite as to how slow or rapid release may be considered "slow or rapid release", "rapidly", "rapid, immediate.. slow, timed, target, pseudo-first order, ...second order and/or delayed release..", and "rapid release" or "a delayed but rapid release".

The expression "a period of time " in claim 14 renders the claim indefinite. The expression "a period of time " is not defined by the claim. The expression "a period of time " is unclear as to how long may be considered "a period of time ".

The expression "sufficient to enhance the therapeutic benefit " in claim 14 renders the claim indefinite. The expression "sufficient to enhance the therapeutic benefit " is not defined by the claim. The expression "sufficient to enhance the

therapeutic benefit " is unclear as to what may be considered "sufficient to enhance the therapeutic benefit ".

The expression "..one drug... the other drug " in claims 22-23 renders the claim indefinite. The expression "..one drug... the other drug " is not defined by the claim. The expression "..one drug... the other drug " is unclear as to which drug may be considered "one drug" or "the other drug ".

Claims 7-8 and 16-17 contain the trademark/trade name, e.g., SOMA^{R}, SC-5766. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular active agents herein and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 10-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al. (N, PTO-892).

Burch et al. teaches that COX-II inhibitors such as rofecoxib (VIOXX or MK-966) are known to be useful in a composition and a method of treating pain. Burch et al. teaches that the composition therein comprising a COX-II inhibitor can also be combined with other active agents , e.g., other analgesic agents, or pharmaceutical expcipients, e.g., colorant and flavorant. Burch et al. further teaches various dosage forms, e.g., tablet, capsules and gelcaps that may control release of the active ingredients therein. See title and abstract, page 5 lines 7-8, page 13 lines 25-27, page 14 lines 4 and 23-30, page 23 and claim 10.

The prior art does not expressly disclose that the employment of a COX-II inhibitor such as rofecoxib in combination with a muscle relaxant such as pridinol in a pharmaceutical composition or dosage. The prior art does also not expressly disclose the effective amounts of active agents in the composition herein to be administered, e.g., the weight ratio of a COX-II inhibitor and a muscle relaxant.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a COX-II inhibitor such as rofecoxib in combination with a muscle relaxant such as pridinol in a pharmaceutical composition or dosage, and to optimize the effective amounts of active agents in the composition herein to be administered, e.g., the weight ratio of a COX-II inhibitor and a muscle relaxant.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a COX-II inhibitor such as rofecoxib in combination with a muscle relaxant such as pridinol in a pharmaceutical composition or dosage since COX-II inhibitors such as rofecoxib are known to be useful in a composition or dosage and a method of treating pain. Moreover, muscle relaxants such as pridinol are well known to be useful alone or in combination with conventional analgesics for the treatment of pain. Therefore, one of ordinary skill in the art would have reasonably expected that combining a COX-II inhibitor such as rofecoxib and a muscle relaxant such as pridinol known useful for the same purpose in a composition to be administered would improve the therapeutic effect for treating pain. Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Since all active composition components herein are known to useful to treat pain, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
September 13, 2001

MINNA MOEZIE, J.D.
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